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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/018,770      | 12/17/2001  | Yoshihito Ikeda      | F-7178              | 2012             |

277 7590 06/21/2005

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |                                       |                                     |  |
|---|---------------------------------------|-------------------------------------|--|
| <b>Advisory Action</b><br><b>Before the Filing of an Appeal Brief</b> | <b>Application No.</b><br>10/018,770  | <b>Applicant(s)</b><br>IKEDA ET AL. |  |
|   | <b>Examiner</b><br>Francisco C. Prats | <b>Art Unit</b><br>1651             |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 31 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,4,6-8,10-14 and 19.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

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**ATTACHMENT TO ADVISORY ACTION**

The response filed May 31, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

All of applicant's argument has been fully considered but is not persuasive of error.

While it is noted that JP '279 does not describe any stability problems with PC-SOD, one of ordinary skill in the art clearly would have recognized that proteins in general are degraded over time by denaturation. This fact is supported by the disclosure of JP '882, page 3 of translation, last paragraph, which also discloses that SOD denatures during the freeze drying process. There is nothing in the prior art suggesting that the known normal degradation of proteins through denaturation does not occur in lecithin-derived proteins, such as PC-SOD.

Moreover, the avoidance of dimerization of SOD is not the sole reason provided in JP '882 for adding disaccharides to freeze-dried SOD preparations. Rather, JP '882 clearly discloses that the purpose of adding disaccharides, such as the sucrose recited in the claims under examination, was to avoid denaturation which occurs during the process of freeze-drying SOD. See, JP '882, translation, pages 3-5. Further still, JP

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'279 clearly describes the use of PC-SOD in freeze-dried applications. See Machine Translation, page 18, paragraph [0028]. Thus, the artisan of ordinary skill, recognizing from JP '882 that addition of sucrose to the freeze-drying mixture of SOD avoids the denaturation problems accompanying the SOD freeze drying process, clearly would have been motivated to have added sucrose to the freeze-drying mixture of the PC-SOD of JP '279, so as to avoid any denaturation of the PC-SOD. Recognizing that the protein portion of the PC-SOD of JP '279 was the same as the protein portion of the SOD of JP '882, the artisan of ordinary skill would have reasonably expected the freeze drying process of JP '882 to have been applicable to the freeze drying process of JP '279. The rejection of record must therefore be maintained.

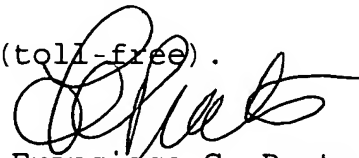
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats  
Primary Examiner  
Art Unit 1651

FCP